



# SO MUCH GOES INTO WHO I AM

HIV MEDICINE IS ONE PART OF IT.



## Kalvin Taking DOVATO

### What is DOVATO?

DOVATO is a complete prescription regimen to treat HIV-1 in adults who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines when their doctor determines they meet certain requirements.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about DOVATO?

If you have both HIV-1 and hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

- **Resistant HBV infection.** Your healthcare provider will test you for HBV infection before you start treatment with DOVATO. If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with DOVATO and become harder to treat (resistant). It is not known if DOVATO is safe and effective in people who have HIV-1 and HBV infection.

DOVATO.com

Please see Important Safety Information throughout this brochure, including an important warning on worsening of hepatitis B infection. Please see Important Facts about DOVATO on page 15.

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## ABOUT DOVATO

DOVATO is the **only** complete HIV treatment with just 2 medicines in 1 pill that controls HIV for adults who are new to treatment or those who are replacing their current regimen.

To learn how quickly DOVATO gets people new to treatment to undetectable\* or to find out more about DOVATO as a replacement option, visit [www.dovato.com/what-is-dovato](http://www.dovato.com/what-is-dovato)

\*Undetectable means reducing the HIV in your blood to very low levels (less than 50 copies per mL).

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What is the most important information I should know about DOVATO? (cont'd)

If you have both HIV-1 and hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including: (cont'd)

- Do not stop DOVATO without first talking to your healthcare provider. If you stop taking DOVATO, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

#### Who should not take DOVATO?

- Do not take DOVATO if you:
  - have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
  - take dofetilide.



“Being undetectable empowered me to have open conversations about my status.”

**Luciano**  
Taking DOVATO

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Reaching and staying undetectable has always been a key goal of treatment. And simply put, it means this: the amount of HIV in the blood is below the level that can be measured by a lab test.

 **Dovato**  
dolutegravir 50 mg/  
lamivudine 300 mg tablets

## WHAT DOES U=U MEAN?

### **U=U stands for Undetectable equals Untransmittable.**

According to the DHHS, people living with HIV who reach and stay undetectable by taking their HIV medication as prescribed prevent transmitting HIV through sex. First, talk to your doctor about further risks of sexual HIV transmission.

### **How long does someone need to be on HIV treatment before the sexual transmission of HIV is prevented?**

Achieving an undetectable viral load can take time. Taking HIV treatment as prescribed and getting to and staying undetectable for at least 6 months prevents transmitting HIV through sex. Viral load testing should be performed on a regular basis to confirm HIV remains at an undetectable level.

### **Should I still practice safe sex if I am undetectable?**

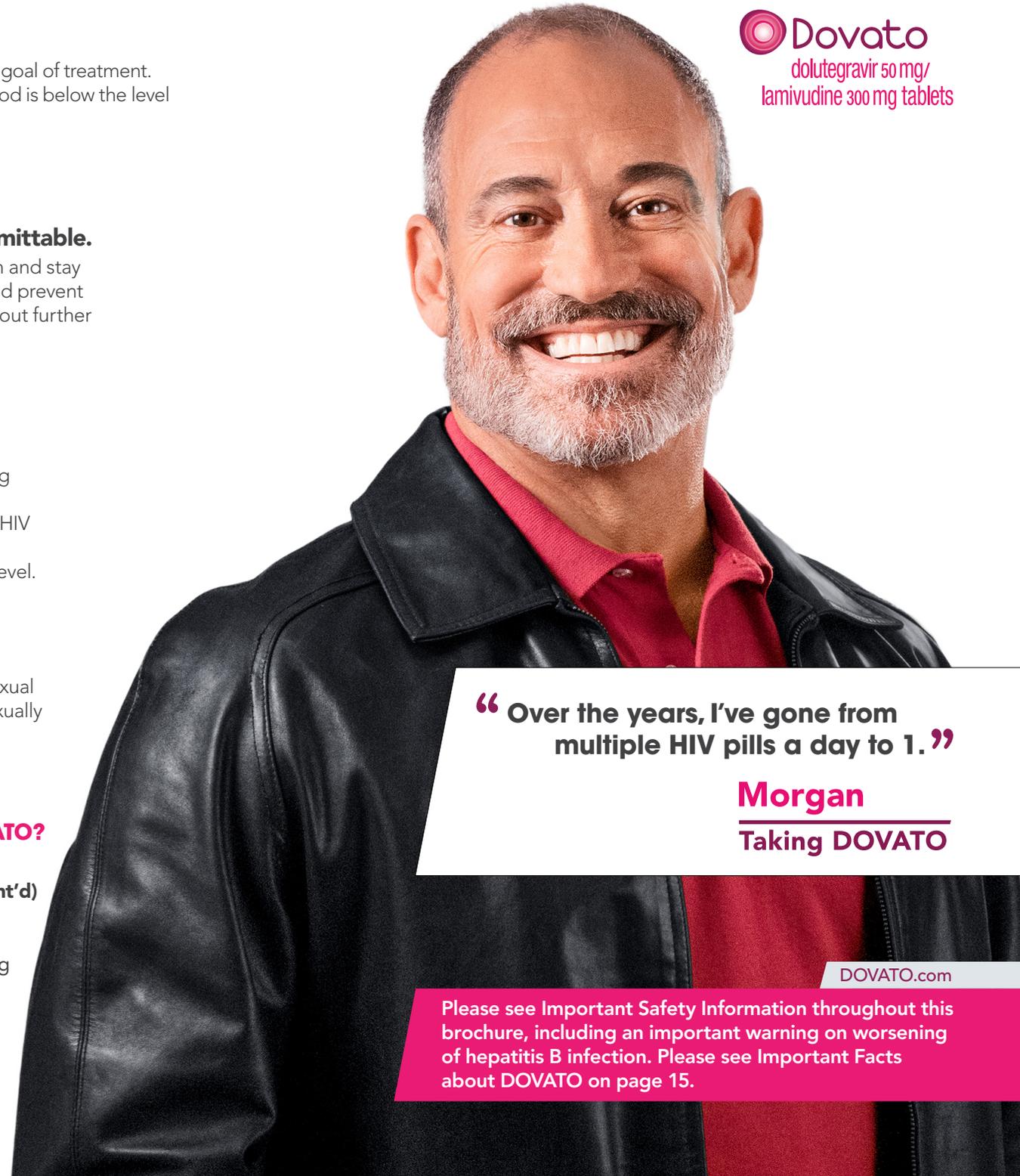
Regardless of status, condoms can help lead a healthy sexual life. Unlike HIV treatment, condoms can prevent other sexually transmitted infections (STIs) and pregnancy.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### **What are other possible side effects of DOVATO? (cont'd)**

#### **DOVATO can cause serious side effects, including: (cont'd)**

- **Liver problems.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with DOVATO. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver.



**“ Over the years, I’ve gone from multiple HIV pills a day to 1. ”**

**Morgan**  
**Taking DOVATO**

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## ABOUT THE STUDIES

—DOVATO was studied in 3 clinical studies—

GEMINI-1 and GEMINI-2 were identical 48-week studies that continued through 96 weeks to determine the effectiveness and safety of DOVATO.

- **A total of 1,433 adults new to HIV treatment were studied**
- **Half started on DOVATO and the other half started on a 3-drug regimen\***

The third study (TANGO) lasted 48 weeks and involved 741 adult patients who were already undetectable with their previous HIV treatment.<sup>†</sup> Approximately half switched to DOVATO, while the other half stayed on that previous treatment.

\*Dolutegravir + tenofovir disoproxil fumarate/emtricitabine.

<sup>†</sup>Tenofovir alafenamide-based 3- or 4-drug regimen.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are other possible side effects of DOVATO? (cont'd)

DOVATO can cause serious side effects, including: (cont'd)

**Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**

- your skin or the white part of your eyes turns yellow (jaundice)
- dark or "tea-colored" urine
- light-colored stools (bowel movements)
- nausea or vomiting
- loss of appetite
- pain, aching, or tenderness on the right side of your stomach area

—Across these studies—



### DOVATO WAS CLINICALLY PROVEN

to control HIV as effectively as an HIV treatment with 3 or 4 medicines by helping people reach and/or stay undetectable.

## SIDE EFFECTS

The most common side effects reported in at least 2% of people taking DOVATO include headache, nausea, diarrhea, trouble sleeping, tiredness, and anxiety.

These are not the only side effects of DOVATO. Always tell your healthcare provider if you experience any side effect.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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## DISCUSSING DOVATO

Consider approaching your next appointment like a C.H.A.T.

**C**ommunicate about your life & schedule

**H**ear about treatment options

**A**sk questions

**T**alk about your health goals

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are other possible side effects of DOVATO? (cont'd)

DOVATO can cause serious side effects, including: (cont'd)

- **Lactic acidosis can also lead to severe liver problems,** which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Liver problems".** You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).



“ Find somebody you can talk to about your treatment and your health. ”

**Alphonso**  
Living with HIV

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## **NEW TO HIV TREATMENT?**

**Ask your doctor these questions.**

- 1.** Could DOVATO be a good option for me to control my HIV?  
What are the benefits and risks?
- 2.** How many medicines are in my different treatment options?
- 3.** Can I reach and then stay undetectable\* with DOVATO?
- 4.** How will taking DOVATO fit into my life and daily schedule?

### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### **What are other possible side effects of DOVATO? (cont'd)**

**DOVATO can cause serious side effects, including: (cont'd)**

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking DOVATO.

\*Undetectable means reducing the HIV in your blood to very low levels (less than 50 copies per mL).

[DOVATO.com](http://DOVATO.com)

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## ON HIV TREATMENT AND UNDETECTABLE?

Ask your doctor these questions.

- 1.** Could fewer medicines\* be a good option for me to continue controlling my HIV? What are the benefits and risks?
- 2.** How many medicines does my current treatment have?
- 3.** Can DOVATO keep me undetectable?†
- 4.** How will taking DOVATO fit into my life and daily schedule?

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are other possible side effects of DOVATO? (cont'd)

DOVATO can cause serious side effects, including: (cont'd)

• **The most common side effects of DOVATO include:**

- headache
- nausea
- diarrhea
- trouble sleeping
- tiredness
- anxiety

These are not all the possible side effects of DOVATO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

\*As compared with 3- or 4-drug regimens.

†Undetectable means reducing the HIV in your blood to very low levels (less than 50 copies per mL).

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To meet LáDeia and others who have inspiring stories about learning to live with HIV, visit [DOVATO.com](http://DOVATO.com)

### IMPORTANT SAFETY INFORMATION (cont'd) What should I tell my healthcare provider before taking DOVATO?

Before you take DOVATO, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- are pregnant or plan to become pregnant. One of the medicines in DOVATO (dolutegravir) may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than DOVATO if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
  - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with DOVATO.
  - If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with DOVATO.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with DOVATO.
- are breastfeeding or plan to breastfeed.  
**Do not breastfeed if you take DOVATO.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - One of the medicines in DOVATO (lamivudine) passes into your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.



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## COULD DOVATO BE RIGHT FOR YOU?

Ask your doctor to find out.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What should I tell my healthcare provider before taking DOVATO? (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with DOVATO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DOVATO.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take DOVATO with other medicines.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please read the Patient Information for DOVATO and discuss it with your healthcare provider.

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“ I am not letting my status take away my *umph* to live...I don't want to live life with coulda, shoulda, woulda. ”

**LáDeia**  
Living with HIV

DOVATO.com

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## LEARN MORE ABOUT DOVATO

[DOVATO.com](https://www.dovato.com)

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Check out ways to access your prescribed ViiV Healthcare medications

Insurance Review

Financial Assistance Programs<sup>a</sup>

Call to speak to an Access Coordinator

Get support from ViiVConnect



1-844-588-3288 (toll-free)  
Monday-Friday, 8AM-11PM (ET)

[LEARN MORE](#)

<sup>a</sup>Subject to eligibility and program terms and conditions;  
ViiVConnect programs do not constitute health insurance.

## IMPORTANT FACTS

This is only a brief summary of important information about DOVATO and does not replace talking to your healthcare provider about your condition and treatment.

(doe VAH toe)

### MOST IMPORTANT INFORMATION ABOUT DOVATO

If you have both human immunodeficiency virus-1 (HIV-1) and hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

- **Resistant HBV infection.** Your healthcare provider will test you for HBV infection before you start treatment with DOVATO. If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with DOVATO and become harder to treat (resistant). It is not known if DOVATO is safe and effective in people who have HIV-1 and HBV infection.
- **Worsening of HBV infection.** If you have HIV-1 and HBV infection, your HBV may get worse (flare-up) if you stop taking DOVATO. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death.
  - Do not run out of DOVATO. Refill your prescription or talk to your healthcare provider before your DOVATO is all gone.
  - **Do not stop DOVATO without first talking to your healthcare provider.** If you stop taking DOVATO, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

### ABOUT DOVATO

- DOVATO is a prescription medicine that is used without other HIV-1 medicines to treat HIV-1 infection in adults:
  - who have not received HIV-1 medicines in the past, or
  - to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if DOVATO is safe and effective in children.

### DO NOT TAKE DOVATO IF YOU

- have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
- take dofetilide.

### BEFORE TAKING DOVATO

Tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- are pregnant or plan to become pregnant. One of the medicines in DOVATO (dolutegravir) may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than DOVATO if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
  - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with DOVATO.
  - If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with DOVATO.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with DOVATO.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take DOVATO.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - One of the medicines in DOVATO (lamivudine) passes into your breastmilk.
  - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### BEFORE TAKING DOVATO (CONT'D)

Some medicines interact with DOVATO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DOVATO.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take DOVATO with other medicines.

### POSSIBLE SIDE EFFECTS OF DOVATO

DOVATO can cause serious side effects, including:

- **Those in the “Most important information about DOVATO” section.**
- **Allergic reactions. Call your healthcare provider right away if you develop a rash with DOVATO. Stop taking DOVATO and get medical help right away if you develop a rash with any of the following signs or symptoms:** fever; generally ill feeling; tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of the skin; redness or swelling of the eyes; swelling of the mouth, face, lips, or tongue; problems breathing.
- **Liver problems.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with DOVATO. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver. **Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:** your skin or the white part of your eyes turns yellow (jaundice); dark or “tea-colored” urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; and/or pain, aching, or tenderness on the right side of your stomach area.
- **Too much lactic acid in your blood (lactic acidosis).** Lactic acidosis is a serious medical emergency that can lead to death. **Tell your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:** feel very weak or tired; unusual (not normal) muscle pain; trouble breathing; stomach pain with nausea and vomiting; feel cold, especially in your arms and legs; feel dizzy or lightheaded; and/or a fast or irregular heartbeat.
- **Lactic acidosis can also lead to severe liver problems,** which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under “Liver problems.” You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).**
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking DOVATO.
- **The most common side effects of DOVATO include:** headache; nausea; diarrhea; trouble sleeping; tiredness; and anxiety.

These are not all the possible side effects of DOVATO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### GET MORE INFORMATION

- Talk to your healthcare provider or pharmacist.
- Go to [DOVATO.com](http://DOVATO.com) or call 1-877-844-8872, where you can also get FDA-approved labeling.

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